

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WYETH,)	
)	
Plaintiff,)	
)	
v.)	C. A. No. 06-222 (JJF)
)	
IMPAX LABORATORIES, INC.,)	
)	
Defendant.)	

**WYETH'S OPENING BRIEF IN SUPPORT OF ITS MOTION TO STRIKE
IMPAX'S UNENFORCEABILITY AND UNCLEAN HANDS AFFIRMATIVE
DEFENSES UNDER FED. R. CIV. P. 12(f), AND TO DISMISS IMPAX'S
UNENFORCEABILITY COUNTERCLAIMS UNDER FED. R. CIV. P. 12(b)(6)**

MORRIS, NICHOLS, ARSHT &
TUNNELL LLP
Jack B. Blumenfeld (#1014)
Karen Jacobs Loudon (#2881)
1201 N. Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
Attorneys for Plaintiff Wyeth

OF COUNSEL:

Basil J. Lewris
Linda A. Wadler
Finnegan, Henderson, Farabow,
Garrett & Dunner, L.L.P.
901 New York Avenue, N.W.
Washington, D.C. 20001
(202) 408-4000

May 12, 2006

TABLE OF CONTENTS

NATURE AND STAGE OF PROCEEDINGS	1
SUMMARY OF ARGUMENT	1
STATEMENT OF FACTS	1
ARGUMENT	4
A. If Impax’s Unenforceability/Unclean Hands Allegations Relate To Alleged Inequitable Conduct or Fraud, They Do Not Meet The Particularity Requirement of Rule 9(b).....	5
B. If Impax’s Unenforceability/Unclean Hands Allegations Relate To Other Alleged Misconduct, They Do Not Satisfy The Fair Notice Requirement of Rule 8(a).....	6
C. The Court Should Strike Impax’s Unenforceability/Unclean Hands Defenses And Dismiss Impax’s Unenforceability Counterclaims.....	7
CONCLUSION.....	9

TABLE OF AUTHORITIES

Cases

<i>Advanced Cardiovascular Sys., Inc. v. Medtronic, Inc.</i> , No C-95-3577 DLJ, 1996 WL 467293 (N.D. Cal. July 24, 1996).....	8
<i>American Top English v. Lexicon Marketing (USA), Inc.</i> , 2004 No. 03 C 7021, WL 2271838 (N.D. Ill. Oct. 4, 2004)	5, 6, 8
<i>Bristol-Myers Squibb Co. v. Ivax Corp.</i> , 77 F. Supp. 2d 606 (D.N.J. 2000)	8
<i>Conley v. Gibson</i> , 355 U.S. 41 (1957).....	6
<i>EMC Corp. v. Storage Tech. Corp.</i> , 921 F. Supp. 1261 (D. Del. 1996).....	5
<i>France Telecom S.A. v. Novell, Inc.</i> , No. 102-437-GMS, 2002 WL 31355255 (D. Del. Oct. 17, 2002)	6
<i>General Motors Corp. v. New A.C. Chevrolet, Inc.</i> , 263 F.3d 296 (3d Cir. 2001).....	7
<i>Honeywell Int'l, Inc. v. Universal Avionics Sys. Corp.</i> , 398 F. Supp. 2d 305 (D. Del. 2005).....	4, 7
<i>Intel Corp. v. Hyundai Electronics Am., Inc.</i> , 692 F. Supp. 1113 (N.D. Cal. 1987)	6
<i>Jones Apparel Group, Inc. v. Piccone</i> , No. 94 CIV. 0754 LMM, 1994 WL 260767 (S.D.N.Y. June 8, 1994)	6
<i>McCracken v. Raghbir</i> , No. 02-1482 JJF, 2004 WL 2326378 (D. Del. Oct. 7, 2004).....	5
<i>Microsoft Corp. v. Jesse's Computers & Repair, Inc.</i> , 211 F.R.D. 681 (M.D. Fla. 2002).....	8
<i>Morse v. Lower Merion School District</i> , 132 F.3d 902 (3d Cir. 1997).....	7
<i>Qarbon.com Inc. v. eHelp Corp.</i> , 315 F. Supp. 2d 1046 (N.D. Cal. 2004)	8

<i>Yash Raj Films (USA) Inc. v. Atlantic Video,</i> No. 03 C 7069, 2004 WL 1200184 (N.D. Ill. May 28, 2004)	8
--	---

Statutes

21 U.S.C. § 355(j)(2)(A)(vii)(IV)	3
35 U.S.C. § 271(e)(2)(A)	3
Fed. R. Civ. P. 8(a)	1, 6, 7, 8
Fed. R. Civ. P. 9(b)	1, 5, 9
Fed. R. Civ. P. 12(b)(6).....	1, 4, 7, 8
Fed. R. Civ. P. 12(f).....	1, 4, 7, 8

NATURE AND STAGE OF PROCEEDINGS

Wyeth filed this patent infringement action against Impax Laboratories, Inc. ("Impax") on April 5, 2006 (D.I. 1). Impax filed its Answer and Counterclaims on April 25, 2006 (D.I. 7). Wyeth has moved to strike Impax's Fourth Affirmative Defense of unenforceability due to unclean hands and to dismiss Impax's Counterclaims that seek a declaration that the patents-in-suit are unenforceable. This is Wyeth's opening brief in support of its motion.

SUMMARY OF ARGUMENT

In its answer to Wyeth's complaint for patent infringement, Impax baldly asserts unenforceability due to "unclean hands" as an affirmative defense, and alleges counterclaims of unenforceability, without any explanation. Impax's bare-bones unenforceability defenses and counterclaims, which do not allege *any* facts to support them, are not pled with the particularity required by Fed R. Civ. P. 9(b), and do not provide fair notice of Impax's claims as required by Fed R. Civ. P. 8(a). These defenses and counterclaims, therefore, should be stricken and dismissed pursuant to Fed. R. Civ. P. 12(f) and 12(b)(6).

STATEMENT OF FACTS

The patents-in-suit¹ broadly disclose a method for treating patients with venlafaxine-responsive disorders (*e.g.*, major depression) by administering once a day an extended release formulation that provides therapeutic blood plasma concentrations of venlafaxine over twenty-four hours having either peak blood plasma levels of venlafaxine

¹ The patents-in-suit are U.S. Patent Nos. 6,274,171 B1; 6,403,120 B1; and 6,419,958 B2 (collectively, the "patents-in-suit").

that are reached in a certain time period, or alternatively, peak blood plasma levels reaching no more than a certain concentration of venlafaxine. The patents set forth exemplary embodiments of extended release formulations for use in the claimed methods.

Wyeth first sold venlafaxine for the treatment of depression in 1994 as an immediate release (“IR”) formulation, under the name Effexor[®]. While Effexor[®] was a potent antidepressant, its use was hampered by two significant limitations. First, because of the relatively short half-life of venlafaxine, patients had to take Effexor[®] two or three times a day, which negatively impacted patient compliance. Second, the side effects of nausea and vomiting associated with Effexor[®] made many patients either unable to continue treatment, or unable to take adequate doses. As a result, doctors and others gave the product the pejorative nickname “Side-Effexor.”

Wyeth started its development of an extended release form of venlafaxine even before Effexor[®] was launched. Wyeth succeeded in those efforts, applied for patent protection for its discovery, and launched extended release Effexor[®] XR (a commercial embodiment of the patents-in-suit) in November 1997. Unlike the IR form of venlafaxine, Effexor[®] XR can be taken once a day, resulting in improved patient compliance. Further, Effexor[®] XR is better tolerated than Effexor[®], making nausea and vomiting less of a problem. As a result of the once a day dosing and better tolerability, more patients are able to stay on the drug and achieve remission. Unlike Effexor[®], U.S. sales of which plateaued several years after launch at about \$225 million per year, U.S. sales of Effexor[®] XR have continued to rise, with annual sales today exceeding \$2 billion. It was the inventions of the patents-in-suit that finally unlocked the true potential of venlafaxine.

In an effort to capitalize on the commercial success of Effexor[®] XR, Impax filed an abbreviated new drug application (“ANDA”) that seeks approval, prior to the expiration of the patents-in-suit, to market a generic copy of Effexor[®] XR. Impax submitted a so-called “Paragraph IV” certification as to the patents-in-suit, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), which constitutes an act of patent infringement.² Impax did not allege that the patents-in-suit are invalid or unenforceable in the Paragraph IV Certification. Wyeth instituted this patent infringement action against Impax within forty-five days of receipt of Impax’s statutory notice. [D. I. 1]

Now, in its answer to Wyeth’s complaint, Impax has asserted, *inter alia*, unenforceability due to “unclean hands” as an affirmative defense to Wyeth’s infringement claims. [D. I. 7 at 7 ¶ 47.] Impax also has asserted counterclaims seeking a declaration of unenforceability as to each of the patents-in-suit. [*Id.* at 10 ¶¶ 67-69.] Impax’s pleading, however, provides no basis for those allegations. The answer does not mention any prior art or allege any misconduct before the U.S. Patent and Trademark Office. It does not make any allegations of bad faith or unconscionability. It does not connect “unenforceability” or “unclean hands” to any action, let alone any action by Wyeth or any action that is related to any claim in this lawsuit. Simply put, Impax merely states the defenses, “unenforceability” and “unclean hands,” without explaining the basis for those defenses.

² 35 U.S.C. § 271(e)(2)(A) provides that it is an act of infringement to submit an ANDA to the FDA "for a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug . . . product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent."

In sum, Impax's bald assertions of "unenforceability" and "unclean hands" are mere legal conclusions devoid of any factual allegations to support them or to which Wyeth can reasonably be expected to respond. These defenses should be stricken pursuant to Fed. R. Civ. P. 12(f) as insufficiently pled. Impax's unenforceability counterclaims likewise should be dismissed pursuant to Fed. R. Civ. P. 12(b)(6) for failure to state a claim upon which relief can be granted.

ARGUMENT

This Court has observed that "a patentee's infringement suit is presumptively in good faith and that this presumption can be rebutted only by clear and convincing evidence." *Honeywell Int'l, Inc. v. Universal Avionics Sys. Corp.*, 398 F. Supp. 2d 305, 314 (D. Del. 2005) (*quoting Handgards, Inc. v. Ethicon, Inc.*, 601 F.2d 986, 996 (9th Cir. 1979)). Impax's bald, conclusory allegations of unenforceability and unclean hands are thus particularly deficient, because they do not allege any fraud or bad faith or provide any context for such allegations.

To prove the defense of "unclean hands," Impax must establish that Wyeth "conducted [itself] as to shock the moral sensibilities of the judge," and that such shocking conduct "has immediate and necessary relation to the equity that [plaintiff] seeks in respect of the matter in litigation" *Honeywell Int'l, Inc.*, 398 F. Supp. 2d at 310 (internal citations omitted).

Here, Impax has identified no conduct by Wyeth upon which it relies, much less "shocking" conduct that could implicate a charge of unclean hands. Impax's unenforceability and unclean hands defenses, therefore, should be stricken and its unenforceability counterclaims dismissed.

A. If Impax's Unenforceability/Unclean Hands Allegations Relate To Alleged Inequitable Conduct Or Fraud, They Do Not Meet The Particularity Requirement of Rule 9(b)

Impax has made no allegation of inequitable conduct in connection with the procurement of the patents-in-suit. If Impax's naked allegations of unenforceability and unclean hands somehow are intended to be a surrogate for alleging inequitable conduct, then Impax plainly has not met the heightened particularity requirement of Rule 9(b). *See EMC Corp. v. Storage Tech. Corp.*, 921 F. Supp. 1261, 1263 (D. Del. 1996) (Farnan, J.) ("As the Court has previously ruled, the particularity requirement of Rule 9(b) applies to inequitable conduct charges."). Rule 9(b) at a minimum requires pleadings to "disclose the name of the relevant prior art and disclose the acts of the alleged fraud." *Id.* Impax has done neither: it does not mention any prior art, and does not allege any acts of fraud.

To the extent Impax's unenforceability/unclean hands allegations are instead intended to relate to other unspecified acts of fraud, they are also subject to Rule 9(b). *See, e.g., McCracken v. Raghbir*, No. 02-1482 JJF, 2004 WL 2326378, at *2-*3 (D. Del. Oct. 7, 2004) (Farnan, J.) (granting motion to dismiss for failure to plead fraud claim with particularity required by Rule 9(b)); *American Top English v. Lexicon Marketing (USA), Inc.*, No. 03 C 7021, 2004 WL 2271838, at *11 (N.D. Ill. Oct. 4, 2004) ("If American suggests Lexicon committed fraud, the conclusory allegation that Lexicon acted with unclean hands fails to meet the particularity requirements of Fed. R. Civ. P. 9(b)."). While Rule 9(b) does not require a party to plead every detail of the fraud, there must be some "precision and some measure of substantiation into [the pleader's] allegations of fraud.'" *McCracken*, 2004 WL 2326378 at *2 (*quoting In re Rockefeller Ctr. Prop. Inc., Sec. Litig.*, 311 F.3d 198, 216 (3d Cir. 2002) (*quoting In re Nice Systems, Ltd. Sec. Litig.*,

135 F. Supp. 2d 551, 577 (D.N.J. 2001)). Impax has not provided any “precision” for, or “measure of substantiation” of, its allegations. Indeed, it has offered no explanations or facts at all.

Thus, to the extent Impax’s unenforceability/unclean hands allegations relate to inequitable conduct or fraud, they do not meet the particularity requirement of Rule 9(b).

B. If Impax’s Unenforceability/Unclean Hands Allegations Relate To Other Alleged Misconduct, They Do Not Satisfy The Fair Notice Requirement of Rule 8(a)

Fed. R. Civ. P. 8(a) requires a pleading to contain a “short and plain” statement of a claim or defense, which provides “fair notice of what the . . . claim is and the grounds upon which it rests.” *Conley v. Gibson*, 355 U.S. 41, 47 (1957).

Even if Impax’s unenforceability/unclean hands allegations are somehow intended to relate to something less than fraud, Impax’s pleadings are still deficient because they do not allege any acts of bad faith, describe any alleged misconduct, or provide any other context for Impax’s allegations of unclean hands or unenforceability. Courts in several jurisdictions clearly have required the unclean hands defense to be pled with at least some measure of particularity. *See American Top English*, 2004 WL 2271838, at *11 (“Unclean hands is an equitable defense that must be pled with the specific elements required to establish the defense.”); *Jones Apparel Group, Inc. v. Piccone*, No. 94 CIV. 0754 LMM, 1994 WL 260767, at *4-*5 (S.D.N.Y. June 8, 1994) (striking unclean hands defense and dismissing unclean hands counterclaims for failure to make specific allegations of bad faith); *Intel Corp. v. Hyundai Electronics Am., Inc.*, 692 F. Supp. 1113, 1117 (N.D. Cal. 1987) (“In the case at hand, Intel should at least be notified of what the alleged defense of unclean hands refers to.”); *cf. France Telecom S.A. v. Novell, Inc.*, No. 102-437-GMS, 2002 WL 31355255, at *2 (D. Del. Oct. 17,

2002) (finding unclean hands defense described in “six short paragraphs stating the basis for the unclean hands defense, including the context of the alleged misconduct” as meeting the pleading requirements of Rule 8(a)). Impax’s bald allegations of unenforceability and unclean hands do not provide Wyeth with any notice at all of the basis for Impax’s claims.

Impax’s unenforceability/unclean hands allegations are further deficient because they do not allege any “unconscionable” acts having an “immediate and necessary” nexus to the equity that Impax seeks in this litigation. *Honeywell Int’l, Inc.*, 398 F. Supp. 2d at 311. Impax does not provide any facts at all, let alone allege any acts that it characterizes as unconscionable, or allege any nexus between any alleged facts and the relief it seeks. Impax’s unenforceability/unclean hands allegations fail for this reason as well.

C. The Court Should Strike Impax’s Unenforceability/Unclean Hands Defenses And Dismiss Impax’s Unenforceability Counterclaims

The Court may strike “any insufficient defense” and dismiss a counterclaim for “failure to state a claim upon which relief can be granted.” Fed. R. Civ. P. 12(f), 12(b)(6). A pleading devoid of grounds or explanation for an allegation, such as here, cannot support that allegation and, therefore, should be stricken (if a defense) or dismissed (if a counterclaim).

A pleading that fails to allege facts that, if true, would support the pleading must fail as both an affirmative defense and a counterclaim. The Third Circuit has made clear that “minimalist, conclusory allegations . . . do not suffice to cross the 12(b)(6) threshold.” *General Motors Corp. v. New A.C. Chevrolet, Inc.*, 263 F.3d 296, 333 (3d Cir. 2001); *Morse v. Lower Merion School District*, 132 F.3d 902, 906 (3d Cir. 1997) (court need not credit “‘bald assertions’ or ‘legal conclusions’ when deciding a motion to

dismiss [under Rule 12(b)(6)].”) (internal citation omitted); *see also Bristol-Myers Squibb Co. v. Ivax Corp.*, 77 F. Supp. 2d 606, 610 (D.N.J. 2000) (in evaluating motion to dismiss under Rule 12(b)(6), courts “will not accept unsupported conclusions, unwarranted inferences, or sweeping legal conclusions cast in the form of factual allegation.”).

Courts have likewise held that a defense should be stricken under Rule 12(f) if it fails to allege sufficient facts. *See American Top English*, 2004 WL 2271838, at *10 (“[a]ffirmative defenses that are simply ‘bare bones conclusory allegations’ do not meet [Rule 8(a)’s] standard and must be stricken”; affirmative defense of unclean hands stricken); *Yash Raj Films (USA) Inc. v. Atlantic Video*, No. 03 C 7069, 2004 WL 1200184 at *2 (N.D. Ill. May 28, 2004) (“Simply naming a legal theory without indicating how it is connected to the case at hand is not sufficient to withstand a motion to strike”; affirmative defense of unclean hands stricken); *Qarbon.com Inc. v. eHelp Corp.*, 315 F. Supp. 2d 1046, 1049-50 (N.D. Cal. 2004) (“A reference to a doctrine, like a reference to statutory provisions, is insufficient notice [under Rule 8(a)]”; affirmative defense of unclean hands stricken); *Advanced Cardiovascular Sys., Inc. v. Medtronic, Inc.*, No C-95-3577 DLJ, 1996 WL 467293, at *13 (N.D. Cal. July 24, 1996) (striking affirmative defense of unclean hands because defendant's answer did not provide any factual basis for the allegation); *Microsoft Corp. v. Jesse’s Computers & Repair, Inc.*, 211 F.R.D. 681, 684 (M.D. Fla. 2002) (striking affirmative defense of copyright misuse for alleging bare conclusion of misuse and failing to allege any facts in support of the defense).

In its answer, Impax has merely alleged a legal conclusion that Wyeth's patents-in-suit are "unenforceable because of Wyeth's unclean hands." As explained above, it is totally unclear from Impax's pleading whether Impax's recitation of "unclean hands" is meant to allege fraud (including inequitable conduct), bad faith, or any other alleged misconduct by Wyeth in connection with any claim in this case. If it is intended to refer to inequitable conduct or fraud, it plainly fails to satisfy the particularity requirement of Rule 9(b). If it is meant to relate to some lesser conduct, Impax has not met even the most basic pleading requirements, and has not alleged *any* facts in support of those allegations. Impax's unenforceability/unclean hands defenses and counterclaims, therefore, should respectively be stricken and dismissed.

CONCLUSION

For the foregoing reasons, Wyeth's motion to strike Impax's unenforceability/unclean hands defenses and dismiss its unenforceability counterclaims should be granted.

MORRIS, NICHOLS, ARSHT & TUNNELL, LLP

/s/ Karen Jacobs Louden

Jack B. Blumenfeld (#1014)
Karen Jacobs Louden (#2881)
klouden@mnat.com
Morris, Nichols, Arsht & Tunnell, LLP
Chase Manhattan Centre, 18th Floor
1201 North Market Street
Wilmington, DE 19899-1347
(302) 658-9200
Attorneys for Plaintiff Wyeth

OF COUNSEL:

Basil J. Lewris, Esq.
Linda A. Wadler, Esq.
Finnegan, Henderson, Farabow,
Garrett & Dunner, L.L.P.
901 New York Avenue, N.W.
Washington, D.C. 20001
(202) 408-4000

May 12, 2006

520159

CERTIFICATE OF SERVICE

I, the undersigned, hereby certify that on May 12, 2006 I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing(s) to the following:

Mary B. Matterer
MORRIS, JAMES, HITCHENS & WILLIAMS, LLP

I also certify that copies were caused to be served on May 12, 2006 upon the following in the manner indicated:

BY HAND

Mary B. Matterer
Morris, James, Hitchens & Williams
222 Delaware Avenue
P.O. Box 2306
Wilmington, DE 19899

BY FEDERAL EXPRESS/SATURDAY DELIVERY

M. Patricia Thayer
John M. Benassi
Jessica R. Wolf
Heller Ehrman LLP
4350 La Jolla Village Dr.
San Diego, CA 92102

/s/ Karen Jacobs Loudon
klouden@mnat.com